REMARKS

Applicants respectfully request reconsideration of the outstanding rejections in view of Applicants' instant claim amendments and the following Remarks. Upon entry of the foregoing amendment, claims 1, 2, 5, 7-12, and 44-53 will remain pending in the application. Claims 1, 51 and 52 are amended herein. Support for the amendments to the claims can be found throughout the specification and in the claims as originally filed, *inter alia*, on page 3, lines 28-33 and page 4, lines 18-21. Applicants respectfully request entry of the above amendments and submit that the above amendments do not constitute new matter. Claims 3, 4, 6, and 13-43 were previously cancelled without prejudice or disclaimer as to the subject matter of the cancelled claims. Applicants respectfully reserve the right to pursue the subject matter of these cancelled claims in one or more continuation or divisional applications.

Statement of Substance of Interview

Applicants respectfully thank Examiner Miller for the courtesy of granting a telephonic interview on May 15, 2009, in the instant application. The interview attendees included the below-listed Representatives (Mrs. Teskin and Mr. Lampe); Mr. Pierre Kary, representative of the Applicant company; and Examiner Miller. During this interview the prior art rejections were discussed, and the distinguishing features of the proposed claim amendments were discussed in relation to the cited Annis, Purkait (EP), Purkait (US) and Breza references. Those points are reflected in more detail in the remarks provided below. The Examiner indicated that these arguments would be fully considered on submission of Applicants' response. For the Examiner's convenience, a bullet-point summary of Applicants' position with respect to the cited references is provided herewith as the Appendix.

Rejections

35 U.S.C. § 112, 1st Paragraph

Claims 1, 2, 5, 7-12 and 44-53 were rejected under 35 U.S.C. § 112, 1st paragraph, as allegedly failing to comply with the enablement requirement. More specifically, it is noted that

claims 1, 51 and 52 each require the polymer to be not water soluble, and further, resistant to degradation. The Examiner has kindly suggested an amendment to address this rejection. Applicants appreciate the Examiner's suggestion, which is incorporated in the instant claim amendments. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1, 2, 5, 7-12 and 44-53 under 35 U.S.C. § 112, 1st paragraph.

35 U.S.C. § 103(a)

(A) Claims 1, 2, 5, 7-12, 45, and 48-53 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Annis *et al.* (EP 0 248 544)(hereinafter "Annis"). The Office Action states that while Annis is silent to mentioning the exact percent of acrylamide and methylene bis-acrylamide (MBA) and their ratio to one another, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the ratio and amount of acrylamide and MBA claimed.

Applicants respectfully disagree and traverse this rejection. Applicants' prior arguments regarding Annis submitted on October 30, 2008, are incorporated by reference in their entirety herein. Applicants also provide the following additional remarks.

As stated in the Office Action, Annis is silent to the exact percent of acrylamide and methylene bis-acrylamide (MBA) and their ratio to one another. Furthermore, Annis is also silent to the complex viscosity of their disclosed hydrogel. According to the Office Action, it would have been obvious to one of ordinary skill in the art at the time of filing to provide the claimed ratio and amount of acrylamide and MBA, as "... it is not inventive to discover the optimum or workable ranges (amounts and ratio of one to another - which would inherently provide the elastic modulus and viscosity, since such as inherent properties of the material) by routine experimentation." *See* Office Action, pages 6-7. Of course, one relevant question regarding this question is, the optimum or workable ranges of what material? Applicants submit that this statement should refer to Annis' hydrogel, and hence the rejection should be interpreted to mean one of ordinary skill in the art would seek to discover the optimum or workable ranges of Annis' hydrogel. In order to do this, Applicants submit that one of ordinary skill in the art

would need to know the purpose or use for which Annis' hydrogel is applied in order to determine the optimum or workable ranges of viscosity.

While Annis does not disclose the optimum or workable ranges of viscosity, Annis is instructive on at least one of the purposes of their hydrogel. More specifically, Annis states:

> Turning to the question of use of the device: this is to involve location as a cuff extending wholly or partly around the proximal urethra to elevate the same from the pelvic floor and thereby restore its capability for response to intra-abdominal pressure as indicated earlier above.

See Annis, col. 3, ll. 49-54 (emphasis added). In other words, Applicants submit that Annis desires their hydrogel to be capable of providing sufficient support to elevate another bodily organ (i.e., the proximal urethra).

Applicants respectfully direct the Examiner's attention to the Declaration of Dr. Robert Lessèl (Appendix A of Applicants' October 30, 2008 response) in which he states:

> A homogenized polymer hydrogel having a complex viscosity of 2 to 60 Pas is fluid-like ... Homogenized non-Newtonian fluids having a complex viscosity of 2 to 60 Pas cannot support their own weight over an extended period of time. Without the constraints of a container or frame, such as [sic] material collapses under its own weight into a formless mass. Such materials cannot be defined in terms of its shape."

See Lessèl Declaration, paragraph 13.

Applicants respectfully note that the claims have previously been amended to recite, in pertinent part, that the hydrogel has a complex viscosity from about 2 to 60 Pas. In light of the points presented above, Applicants submit that one of ordinary skill in the art at the time of the invention would not have achieved or sought to achieve from Annis the complex viscosity set forth in the pending claims because such a complex viscosity at least would not have achieved one of the purposes or uses of Annis' invention, namely to produce a hydrogel capable of providing sufficient support to elevate another bodily organ (i.e., proximal urethra).

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-2, 5, 7-12, 45, and 48-53 under 35 U.S.C. § 103(a) as allegedly being

unpatentable over Annis.

(B) Claims 1-2, 5, 7-12, 44-46, and 48-53 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Purkait (EP 0 895 785)(hereinafter "Purkait EP"). The Office Action states that Purkait EP discloses a composition having the same monomers claimed by Applicants in the same weight percent and same viscosity, but is silent to mentioning the exact percent of acrylamide and methylene bis-acrylamide (MBA). The Office Action states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the ratio and amount of acrylamide and MBA claimed.

Applicants respectfully disagree and traverse this rejection. Applicants' prior arguments regarding Purkait EP submitted on October 30, 2008, are incorporated by reference in their entirety herein. Applicants also provide the following additional remarks.

Applicants note that the claims have been amended to recite that the hydrogel itself is resistant to biological degradation, said hydrogel including a substantial portion of crosslinked acrylamide. As understood from Dr. Lessèl's Declaration, the person skilled in the art would generally understand that the product resulting from the claimed acrylamide polymerization process was as a whole water insoluble. *See* Lessèl Declaration, paragraph 5. In contrast, Purkait EP teaches numerous embodiments including appreciable amounts of non-crosslinked acrylamide (i.e., linear acrylamide). *See*, for example, Purkait EP, paragraphs [0055] - [0060]. According to Dr. Lessèl, "... Purkait teaches that all or almost all of the composite hydrogel is non-crosslinked polyacrylamide. The person skilled in the art knows that non-crosslinked polyacrylamide is water soluble. Purkait accordingly describes a composite hydrogel material wherein the major component is very water soluble." *See* Lessèl Declaration, paragraph 4.

This water solubility enables a "particularly advantageous" characteristic of Purkait EP. According to Purkait EP, "the material should be biocompatible. As used herein biocompatibility means that the material is either excreted from the body, or is easily metabolized into harmless byproducts. Non-metabolized materials must be sufficiently small that they can be transported through membranes and excreted by the body in the urine or fecal matter." *See* Purkait EP, paragraph [0020].

The Office Action states that Purkait EP's hydrogel is considered to be the cross-linked acrylamide composition only. Applicants respectfully disagree and submit that Purkait EP teaches the combination or mixture of linear and cross-linked polyacrylamide, which provides the hydrogel of Purkait EP with attributes such as biodegradability. Applicants submit that Purkait EP does not teach that the hydrogel is produced from cross-linked polyacrylamide alone. If this were the case, Applicants submit that it is very unlikely that the attribute of biodegradability in Purkait EP would be achievable.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-2, 5, 7-12, 44-46, and 48-53 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Purkait EP.

(C) Claims 1-2, 5, 7-12, 44-46, and 48-53 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Purkait (US 5,658,329)(hereinafter "Purkait US"). The Office Action states that Purkait US discloses a composition substantially as claimed, however is silent to mentioning the exact percent of acrylamide and methylene bis-acrylamide (MBA). The Office Action states that Purkait's composition is inherently insoluble and non-degradable when in a cross-linked form- which Purkait discloses the polymer may be cross-linked or non-cross-linked (*citing* to col. 7, ll. 50-52). The Office Action states that it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the ratio and amount of acrylamide and MBA claimed.

Applicants respectfully disagree and traverse this rejection.

As with Purkait EP, Purkait US recites that "the material should be biocompatible. As used herein biocompatibility means that the material is either excreted from the body, or is easily metabolized into harmless byproducts. Non-metabolized materials must be sufficiently small that they can be transported through membranes and excreted by the body in the urine or fecal matter." *See* Purkait US, col. 4, ll. 47-52

Applicants submit that a hydrogel having a polymer component that is only cross-linked polyacrylamide is inconsistent with the biocompatibility set forth as an attribute by Purkait US of

their hydrogel. Accordingly, Applicants submit that one of ordinary skill in the art, understanding the desired attributes of the hydrogel of Purkait US and further understanding that non-cross-linked polyacrylamide is water soluble, would seek to include a reasonably substantial amount of non-cross-linked polyacrylamide in a hydrogel of Purkait US in order to achieve the goal of biocompatibilty. Therefore, one of ordinary skill in the art at the time of the invention would not have sought to produce the claimed invention from Purkait US.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-2, 5, 7-12, 44-46, and 48-53 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Purkait US.

(D) Claims 1-2, 5, 7-12, 44, 45, and 48-53 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Breza *et al.* (US 3,661,659)(hereinafter "Breza").

Applicants respectfully disagree and traverse this rejection.

Applicants note that the claims have been amended to recite that the hydrogel is useful as an endoprosthesis in a mammal. Applicants submit that the disclosure of Breza is broadly directed to "gelled acidic explosive compositions", as indicated in the title. For example, the abstract of Breza states that "the gelling system of this invention finds particular utility in explosive compositions based on an oxidizing agent and one or more fuels or sensitizers." *See* Breza, Abstract. Applicants submit that one of ordinary skill in the art in the medical field at the time of the invention would not have viewed Breza's compositions as suitable for implantation in a mammal.

Applicants submit that one of ordinary skill in the art at the time of the invention would have no reason to modify the teachings of Breza to reach the claimed bio-stable hydrogel that can be used as an endoprosthesis in a mammal, given the teachings of Breza.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-2, 5, 7-12, 44, 45, and 48-53 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Breza.

CONCLUSION

An indication of allowance of all claims is respectfully solicited. Early notification of a favorable consideration is respectfully requested.

Respectfully submitted,

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Date: June 22, 2009

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Appendix

Summary of Applicants' Position Regarding the Cited References

Annis Reference

- Applicants submit that one of ordinary skill in the art at the time of the invention would not have achieved or sought to achieve the complex viscosity set forth in the pending claims because such a complex viscosity at least would not have achieved one of the purposes or uses of Annis' invention, namely to produce a hydrogel capable of providing sufficient support to elevate another bodily organ (i.e., proximal urethra).

Purkait EP Reference

- Applicants submit that Purkait EP does not teach that the hydrogel is produced from cross-linked polyacrylamide alone. If this were the case, Applicants submit that it is very unlikely that the attribute of biodegradability in Purkait EP would be achievable.

Purkait US Reference

- Applicants submit that one of ordinary skill in the art, understanding the desired attributes of the hydrogel of Purkait US and further understanding that non-cross-linked polyacrylamide is water soluble, would seek to include a reasonably substantial amount of non-cross-linked polyacrylamide in a hydrogel of Purkait US in order to achieve the goal of biocompatibilty.

Breza Reference

- Applicants submit that one of ordinary skill in the art in the medical field at the time of the invention would not have viewed Breza's compositions as suitable for implantation in a mammal.